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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,766	01/17/2002	Richard J. Fitzpatrick	1932.1110-001	5568
21005	7590	02/18/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,766

Applicant(s)

FITZPATRICK ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11-19 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/31/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of applicants' arguments and request for extension of time filed 11/04/03.

Information Disclosure Statement

Examiner acknowledges receipt of the non-patent literature, references #s AR-AS, AM2, AN2, AO2, AT-AW, AP2, AQ2, AL3, AM3, AN3, AO3, indicated as not considered in the office action of 07/01/03, is now considered. A copy of updated signed FORM 1449 is enclosed herewith.

Election/Restrictions

Examiner thanks applicants for affirming the elected claims 1-8, 10 and 20-24.

Claim Rejections - 35 USC § 112

1. Claim 4 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of mucositis, reduction in severity and reduction in size of mucositis, does not reasonably provide enablement for prophylaxis/prevention of mucositis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants traverse the above rejection by stating that it is "reasonable to expect that a therapy that successfully treats an active disease state would also be effective in preventing the disease state from developing and/or from becoming established." Applicants also state that one skilled in the art would be able to identify risk factors and begin treatment before symptoms appear and as such, applicants conclude, "it is reasonable to expect that mucositis can be prevented by the claimed method."

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2. Applicant's arguments filed 11/04/03 have been fully considered but they are not persuasive.

There is no evidence that a therapy that successfully treats an active state would also be effective in preventing the disease state. There is no data showing that all X-number of persons identified as having risk factor developing a particular disease state went on to develop the disease state and all the X-number of persons identified as having risk factor developing were successfully treated and 100% of the time failed to develop the disease state. Does identification of the risk factor in a person indicate that the person is 100% free from the disease state and how many pools of persons have been identified as having the risk factor and how many have been treated and have showed presented with absence of the disease state for how long, for the life time of the person?

The standard for prevention is high and applicants have not met the standard. Applicants have not presented overwhelming data to overcome the high standards of prevention. Hence, the examiner provides conclusory statements, and the applicants have not provided the burden of evidence. The burden is thus on the applicants to provide data showing 100% prevention in 100% of the persons identified with the risk factors at 100% of the time and for the life of the person having the risk factor from developing the disease state.

Regarding the issue with the modifications of the formula (II) as claimed, there is no data to show that all the forms of the ionene polymer that meets the formula (II) has been shown by applicants to prevent the disease state from being established in 100% of the cases in 100% of the time and for the life of the persons identified to have the risk factor. Thus the skilled artisan would have to undertake the task of establishing that 100% of the time in 100% of the cases and

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for the life of the person that the various forms of formula (II) prevents the disease condition from developing. The burden is on the applicant to show the prevention.

It is suggested that applicants use inhibition or reduction in the claims.

Double Patenting

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-8, 10 and 20-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-50 of copending Application No. 10/051,765, which is a published application number US 2003/0031644.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are obvious over the claims of the co-pending application. The method of claim 1 differs from the method of claim 42-44 in that in the application treats mucositis or stomatitis whereas the method of claims 42-44 treats microbial infection.

However, the portion of co-pending application supports treating mucositis with polyionene polymers (paragraph 130). Therefore, it would have been obvious to administer the polyionene copolymer to a subject in need thereof. One having ordinary skill in the art would have been motivated to administer the polyionene polymer to a subject in need thereof with the expectation of treating mucositis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants argue that a product and the process of using the product are distinct and are capable of supporting different patents within the art. While this argument is persuasive, a terminal disclaimer is not excluded from applicants' argument.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

